America's Air: If It Ain't Broke, Don't Fix It!

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If it ain't broke, don't fix it. Seldom has that old saw been more applicable than to the current debate over the U.S. Environmental Protection Agency's (EPA's) plans to further reduce the ozone (a smog component) and fine particles (mostly soot) in our air.

The air - even in Southern California - is getting cleaner steadily as a result of existing stringent regulations; the Clean Air Act is working. EPA's own data says so. The proposed regulations fix something that isn't broken, and they are based on incomplete evidence when measured by the proven scientific yardstick. Local attempts to meet the proposed standards could even do more harm than good. How so?

To answer, let me first give a little background on the science of fine particles - the source of most of the controversy. EPA has concluded that a new standard will reduce premature deaths and decrease childhood asthma attacks. It is true that scientists have identified a weak association between airborne particles and human health effects. But this association can be misleading; a cause-and-effect link has not been established.

We all want good air. That is a given. The problem is that no one knows whether controlling fine particles will extend lives or reduce asthma incidence. So little data exists on particles this tiny that we are not sure what all their sources are (natural and manmade) or how human health will be affected if they are reduced.

Recently, I organized two conferences that brought together research scientists, clinicians, regulators and others to discuss the scientific basis for more stringent particle air pollution standards. At both conferences, many scientists expressed the belief that the scientific knowledge of fine particle air pollution - is very incomplete.

When definitive answers are in hand, we will be able to focus efforts on protecting those people affected by measuring and controlling the specific culprits. But a standard adopted on the basis of incomplete knowledge could produce improper control actions that do more harm than good.

EPA estimates that the new rules will cost $8 billion; ultimately paid in costs of energy and goods -- food, automobiles, shelter, clothing and the like. Public health problems could result as resources are diverted away from proven public health initiatives to address a problem that may not exist.

The scientists at EPA are not at fault; they work under political pressure and an antiquated mandate that does not permit them to examine all of the consequences associated with a specific regulation. They work on each pollutant in isolation, which can lead to unreasonable rules.

I know that it is difficult to wait for the needed research for answers that ensure we are not making a big mistake. Scientists tend to promote their own research; regulators fear that they will be criticized for failing to be decisive; advocates seize an opportunity; and politicians don't want the public to think that they are soft on environmental or public health issues. But if premature standards are adopted and proved to be deleterious, all of these groups will be diminished in the eyes of the public.

We do not have a health crisis due to fine particles. The existing standards are working and should be retained while the needed research is performed. In other words, if it ain't broke, don't fix it.

END 585 word count

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TESTIMONY: PRESENTED TO THE U.S. HOUSE OF REPRESENTATIVES; (COMMITTEE ON COMMERCE) Subcommittees on Health and Environment; and Oversight and Investigations

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I am Robert Phalen, Ph.D., of the College of Medicine of the University of California, Irvine. I am a Professor of Community and Environmental Medicine, a faculty member of the Center for Occupational and Environmental Health, and I am the Director of the Air Pollution Health Effects Laboratory (all at the University of California, Irvine).

As former chair of our Medical Human Subjects Research Review Committee, I have seen how early scientific findings often do not survive the test of time. Also, I have recently organized two major international scientific conferences on the health effects of particulate air pollution. Each conference produced a 700-plus page proceedings, plus special peer-reviewed scientific journal issues,[1,2] which I edited. These conferences brought together research scientists, clinicians, regulators and others interested in sharing information and participating in frank discussions regarding the scientific basis for new, more stringent, particulate air pollution standards. At both conferences, many attendees openly expressed the belief that the science on the health effects of particulate air pollution was very incomplete. However, the U.S. EPA has proposed stringent new particulate standards that could have serious economic consequences. I believe that the proposed $PM_{2.5}$ standards are premature and may even be harmful to public health because our knowledge is not complete enough to support responsible control actions. Let me briefly present some of my reasons for this judgement.

Skilled epidemiologists have indeed identified weak associations between airborne particulate mass and human health effects.[3,4] Their studies only point toward a possible cause-and-effect relationship. Before an association can be determined to be a cause, several basic questions must be answered. For example, just three of the essential questions are: What chemical or physical agent(s) is(are) harming people?; Who specifically is harmed by particulate air pollution (what sub-populations)?; and How are they being injured? Or more simply, what is the cause and what is the effect in the hypothesized cause-and-effect relationship? If we had definitive answers to these questions, we could focus our efforts on protecting the specific groups affected, as well as measuring and controlling the specific air-pollutant culprit(s). To answer these questions, along with many others that are relevant, additional scientific disciplines beyond epidemiology are required.[5]

To support the position that the science is incomplete and a new standard is premature, I would like to give a few examples. Atmospheric chemists are just now learning how to sample and analyze the possible key harmful agents in particulate air pollution. Particulate air pollution contains hundreds, perhaps even thousands, of chemical agents. Only a small percentage of these can be effectively monitored and characterized, and many of them are so reactive or volatile that they disappear soon after collection and cannot be analyzed using present technologies. The use of mass (instead of chemical components) as a surrogate measure of toxicity is risky. It may even lead to control strategies that increase health risks. For example, an air standard based upon particulate mass alone force the use of diesel engines (or other types of engines) with lower particulate mass emissions, but with more particles exhausted per mile. This could be catastrophic if particle number, rather than mass, is the primary hazard.[6] Research to deal with the major uncertainties is being planned and initiated as we meet here today.

Toxicology, the science that identifies mechanisms of action and the harmful and safe doses of substances, has not yet been adequately employed to characterize the culprits in particulate air pollution that might be responsible for the hypothesized adverse effects. The critical toxicology research has been identified, and some of it is just getting underway. There are problems in clarifying what components of particulate air pollution might be harmful, but the needed research is going to be conducted at excellent laboratories all around the world, including those of the U.S. EPA. The knowledge that is sorely needed includes identifying the most harmful components and their dose-response characteristics. It is somewhat difficult to understand how experienced toxicologists could support the regulation of chemically-unknown substances ($PM_{2.5}$) with unknown dose-response relationships.

History has demonstrated that early scientific results and early conclusions based upon them often do not hold up to the tests of time and challenge. It is likely that when the research on particulate air pollution is more complete, the proposed $PM_{2.5}$ regulations will be demonstrated to be naive and unwarranted. The stretch from the weak epidemiologic associations and the tenuous bits of information from other scientific disciplines to the enactment of a $PM_{2.5}$ standard is just too great. If the proposed standard is adopted on the basis of such incomplete knowledge, control actions will be taken that could do more harm than good. We face increases in the cost of energy (increasing costs of heating, air-conditioning and gasoline) and of essential goods including food, automobiles, shelter, clothing and many other items that have health-related impacts.[7] In many areas of the country, emissions may need to be cut drastically in order to meet the proposed standards. Serious localized public health problems could result.

I don't believe that the U.S. EPA is at fault for proposing standards before the related science is completed. It has a mandate from Congress that causes it to isolate individual pollutants (which are sometimes ill-defined), to find the most sensitive group of people affected, and then to propose a standard, with a safety factor, to protect that group. Also, the U.S. EPA is expected to incorporate up-to-the-minute (even controversial) new findings in its deliberations. The U.S. EPA has some of the finest scientists in the world, and they should be given a chance to exercise their most prudent judgement, and to take into account all of the health-related consequences (on everyone) of such a regulation. I know that it is difficult to wait for the needed research, but there is really is no alternative. Why is there such a rush to action in this case? Scientists are frequently effective advocates for promoting applications for their own research, regulators may fear that they will be criticized for failing to be decisive, air quality advocates will seize an opportunity such as this, and politicians don't want the public to think that they are soft on environmental or public health issues. But, if premature and deleterious standards are adopted, all of these groups could be diminished in the eyes of the public. The public is becoming aware of the tenuous nature of the scientific evidence for the proposed particulate standard,[8] and the public should insist on more-complete scientific information before being subjected to the financial and other effects of severe new regulations.

We do not presently have a health crisis due to the effects of particulate air pollution. The existing standard should be retained as is, and the needed research base be more firmly established prior to the promulgation of a costly new standard. Thank you.

References:

1. Proceedings of the Colloquium on Particulate Air Pollution and Human Mortality and Morbidity, Inhalation Toxicology 7(1), 1995.
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Attachments:

1. America's air: If it ain't broke, don't fix it. (op-ed article), Orange County Register, Sunday, April 13, 1997.

2. Research needs relating to health effects of exposure to low levels of airborne particulate matter, Proceedings of the Second Colloquium on Particulate Air Pollution

and Human Health, Rocky Mountain Center for Occupational & Environmental Health, University of Utah, Salt Lake City, UT, December 1996, pp. 9-1 to 9-6.

IX. RESEARCH NEEDS SUMMARY

Research Needs Relating to Health Effects of Exposure to
Low Levels of Airborne Particulate Matter

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I. Introduction

Concern over the consistent and reproducible epidemiological associations between particulate air pollution and human mortality and morbidity stimulated a series of two international scientific colloquia. The first was held January 24-25, 1994, in Irvine, CA, and the second was held in Park City, UT, on May 1-3, 1996. Each colloquium was attended by about 200 epidemiologists, toxicologists, chemists, clinicians, regulators and other concerned specialists. At both colloquia, attendees were asked to submit written suggestions for future related research after they had listened to numerous formal papers and after participating in several open discussions. It is important to note that these research suggestions represent snapshots in time of the ideas of a large group of well-informed experts with varied backgrounds; these recommendations do not carry the imprimatur of the colloquium sponsors, any regulatory body or any other agency. This paper summarizes the research suggestions from the second colloquium; a similar paper was published relating to the earlier colloquium (1).

The suggestions from attendees of the second colloquium, over 160 in total, were first sorted into broad categories based on the type of project suggested (epidemiology, toxicology, sampling, etc.), and then similar studies were combined under a single description. Some projects were suggested by 5 or more individuals, most by 2-3 individuals, and about 25% were suggested by only one person. In the summary lists that follow, the projects listed first within each category are those that were most frequently suggested.

II. Research Needs by Category (the projects are not necessarily mutually exclusive)

A. Studies Related to Air-Pollution Epidemiology and Epidemiologic Methods

1. Longitudinal panel studies of morbidity and mortality in healthy and compromised individuals (bronchitis, cardiovascular-compromised, etc.), with personal exposure characterizations.
2. Effects of long-term exposures with extensive data collection, including personal exposures and weather parameters.
3. Studies of the effects of exposure assessment errors on epidemiology study findings.
4. Meta-analyses in which studies are combined in order to identify roles of specific exposure agents.
5. Studies in cities (including those in eastern and western Europe) which have high and low extreme levels of pollutants. Complete monitoring data are required.
6. Investigations of the effects (roles) of personal exposures on epidemiologic findings.
7. Collaborative (between economists and epidemiologists) research which focuses on cost-benefit analyses and health valuations.
8. Comparisons of mortality rates and incidence of diseases for the following: clean and highly-polluted days; clean and highly-polluted cities; and cities that have improving air-quality.
9. Health effects of personal exposures, including studies of hospital deaths (with thorough monitoring of chemical species).

10. Incorporation of autopsy data into epidemiologic investigations.
11. Investigations directed at threshold phenomena.
12. Studies to explain the observed increases in asthma rates in light of improving outdoor air quality.
13. Investigation of population characteristics (as opposed to individual characteristics) in relation to morbidity and mortality.
14. Additional investigations of the roles of non-particulate pollutants in epidemiologic investigations of particulate matter.

B. Occupational Cohort Studies

1. Follow-up of particle-exposed occupational cohorts after retirement to look for chronic illnesses and possible induced sensitivity to environmental particulate air-pollutants.
2. Studies of cohorts with current heavy particle exposures in order to look for excess cardiopulmonary-related morbidity and mortality.

C. Clinical Studies

1. Investigations of pollutant deposition and clearance in subjects with existing pulmonary diseases.
2. Investigations of pollutant effects in sub-populations that are expected to have enhanced sensitivity to particulate air pollutants.
3. Investigations of ventilatory and activity patterns for various types of people.
4. Investigations relating to the possibility of differentiating particulate-caused cardiovascular (and pulmonary) deaths from deaths produced by other causes.

D. Toxicology Studies

1. Mechanism of action studies (hypothesis-driven) that include cardiac effects, as well as pulmonary effects.
2. Investigations of the roles of specific chemical constituents of air-pollution, including transition metals, hydrogen ions, reactive chemical intermediates, and semi-volatile species.
3. Studies of the roles of particulate mass, particulate surface area, and particulate number in relation to biological effects.
4. Development of new animal models that mimic human diseases, or that are more sensitive than existing models.
5. Investigations of ultrafine particles: their deposition, translocation, clearance and effects. (Note that no single accepted definition of ultrafine exists, but in this context, particles with diameters under 0.1 μm is implied.)
6. Studies that investigate medical plausibility hypotheses which can be related to adverse human health effects.
7. Particle deposition and clearance studies in healthy and diseased animal models.
8. Exposures to actual ambient pollutants, or otherwise more-realistic physical and chemical forms of ambient pollutants.
9. Studies of combinations of pollutants (including thermal stress as a co-factor) that contain both particles and gases.
10. Dose-response and threshold studies in animal models that represent sensitive human sub-populations.
11. Studies of interactions of particulate material and oxygen radicals.
12. Long-term studies, including those that relate acute effects to chronic effects.

13. Studies of sensitization to ambient air pollutants.
14. Additional toxicology studies on indoor-source pollutants.
15. Studies of the toxicologic effects of coarse particles. (Note that in this context, coarse particles have diameters larger than 2.5 μm.)
16. In-vitro exposures of respiratory-tract cells to realistic particles.

E. Sampling, Analysis and Exposure Assessment Investigations

1. Improvements in equipment and procedures used for monitoring particle size and composition, including ultrafine particles, and semi-volatile components (especially using denuder-related technology). Also, monitors that are smaller, less expensive and lighter are needed for PM10 and PM2.5 measurements in the field.
2. Gathering of additional data on particulate-matter size distributions and chemical compositions.
3. Studies that correlate indoor and outdoor particulate levels, and that better define personal exposures.
4. Development of continuous (or short averaging time) monitors for PM10 and PM2.5.
5. Studies of source apportionment, and studies leading to improvements in modeling the effects on air pollution of changes in source strengths.
6. Characterizations of indoor exposures, and definition of the inhaled doses to people from indoor air pollutants.
7. Studies of interactions among realistic combinations of air pollutants, including particles and gases (both short-lived and long-lived).
8. Improved personal exposure characterizations.
9. Interactions of viable and non-viable pollutants, including those that are infectious and allergenic.

F. Dosimetry-Related Investigations

1. Development of improved dosimetry models that apply to individuals, rather than simply to an average adult.
2. Basic airway anatomical data that relate to modeling the deposition and fates of particulate and gaseous air pollutants.
3. Improvements in techniques used for assessing potential risks, including more holistic approaches that balance risks from various causes.

III. Practical Considerations

It was clear from some of the written comments that the needed research could not be performed without first solving some practical problems. These practical considerations included the following:

1. A central repository for data, including epidemiologic, toxicologic and atmospheric, is needed so that new studies can be better designed, interpreted and integrated. Also, such a repository would facilitate meta-analyses, and prevent unnecessary duplication.
2. International cooperation should be encouraged, as is required for fostering progress on many aspects of the problem of particulate pollution and human health.
3. Additional funding should be made available for the needed research. This will require the cooperation of local, federal and international governments, of businesses, and of other private agencies.
4. A perpetual Colloquium on Particulate Matter and Human Health, with permanent staff and a world-wide web page, should be seriously considered. A two-year interval between

meetings was the most common recommendation.

5. A two-tiered air monitoring system is needed, in which cities involved in epidemiologic studies have more-complete, research-quality monitoring. Other cities (not involved in studies) would presumably have less expensive monitoring stations that are geared toward evaluating compliance with existing air-pollution regulations.

6. A complete bibliography on all aspects of particulate matter and health should be established and maintained current.

7. EPA's deposition modeling program should continue, and it should have adequate support.

V. Major Unresolved Issues

Few, if any, informed people are likely to doubt the validity of the epidemiologic associations between ambient particulate mass sampling data and data on human mortality and morbidity. However, the reason(s) for this association is (are) currently undergoing intense scientific scrutiny and debate. Experts also disagree on whether or not sufficient evidence against particle mass exists to support intensified mass-based controls. What is at stake is great, because a premature judgement that leads to ineffective costly controls could have a burdensome impact that could seriously wound the trust that the public has for the regulatory and scientific communities. Therefore, it is important to carefully examine all significant issues that are not well understood.

From looking at the preceding lists of research needs, some larger uncertainties can be seen -- some clearly, and some less distinctly. These uncertainties include the following:

A. Who?; What?; and How?

Assuming the excess mortality is real, it is clear that we cannot confidently answer the following three questions: Who is dying?; What agent(s) is (are) killing them?; and How is (are) the causal agent(s) acting? It can be argued that in order to implement regulations that effectively decrease the risk, more-specific information is needed than simply an epidemiological association. It is important to know who is dying. For example, is it only critically-compromised persons in some specific indoor locations, such as hospitals, etc.; or are the victims virtually everyone exposed anywhere in a polluted city? Similarly, what is causing the deaths? Is it the number of sub-tenth μm diameter insoluble particles inhaled over the period of a day? Is it some unique combination, such as an acid-coated particle that contains transition metals? Or is it everything together (all air pollutants) acting as a lethal soup? The answers to these questions could be important in devising efficient and effective control strategies. Also, what is (are) the mechanism(s) of death? Is it upper airway inflammation? Is it alveolar inflammation and interstitial edema? Is it all of the above, plus other causes? Again, intervention strategies could be best designed if these questions can be clearly answered. Many of the previously-identified research needs (if not all of them) are related in one way or another to answering one or more of these questions.

B. Medical Plausibility

Substantial differences of opinion exist on the necessity of establishing a link between particulate exposure and death (or injury). What is meant by "medical plausibility"? At one extreme, it is something similar to a proof in geometry. Given some solid basic assumptions about physics, chemistry and physiology, one might establish an unbroken chain of events (such as pollutant deposition, early response, secondary reactions, organ failure, etc.) at the end of which death or debility is virtually certain. Such logical proofs do exist for many illnesses and poisonings, and when this is the case, intervention (at least in principle) is straightforward. At the other extreme, "plausibility" might simply mean that there is an absence of proof of absurdity.

Intense smog episodes kill people, so why not smaller ones? A substantial fraction of the previously-listed research needs, especially those in the "Toxicology" category, relate to the plausibility question.

C. Defining PM

On the face, particulate matter (PM) seems to be a relatively unambiguous entity; it is just the condensed matter in the air. But two substantial problems exist with this simple definition. First, one can measure PM by total count, total surface area, total mass, non-aqueous mass, insoluble mass, non-biogenic mass, etc., etc. Which is the relevant measure, or which are the relevant measures, for the presumed adverse health effects? Second, the condensed particulate phase is very dynamic; volatiles evaporate and condense; chemical reactions change the composition and mass; the surrounding conditions including temperature, humidity and gaseous compound concentrations also can rapidly change the particulate composition and mass. Is the mass and composition on a filter (at laboratory conditions) the relevant particulate matter, or is the airborne condensed phase as it exists just outside of the human nose (or inside the trachea) most relevant? Several items in the suggested research list, especially in the "Sampling, Analysis and Exposure Assessment" category, relate to this large issue.

D. Effects of Control Strategies

Any control strategy will have several effects; some will be reasonably predictable, and some may not be so predictable. A tightened standard, for example, will possibly produce adjustments in industrial processes, changes in the costs of products, changes in illness patterns, and new atmospheric chemistry processes. What will be the net consequences of all of these changes? The suggested research projects (especially in the "Epidemiology" section) include items that address this important question.

E. Occupational Implications

Historically, the protection of workers from adverse effects has followed strategies that differ substantially from those used in environmental-exposure situations. Specifically, the focus is on individual, rather than mixed, pollutants, and on small, highly-exposed relatively healthy populations. What can be learned from the occupational health literature that helps us to understand environmental exposures, and vice versa?

F. Levels vs. Increments

Much (but not all) of the recent epidemiological research is based not on average air pollutant particulate levels, but on changes (or increments) in the level; the larger the incremental increase in particulate matter, the larger the associated health effects. Does this imply that any level of particulate pollutant, even one as low as a few tens of micrograms, is associated with adverse effects? Research suggestions that involve thresholds, dose-response considerations, and effects of cleaning the air, address this issue.

G. What is the Proper Metric for Compliance?

This question is clearly related to the section, "Defining PM" , and several other suggested research projects directly apply to this question as well. On one hand, because the epidemiologic associations are based on PM10 and PM2.5, such measures (metrics) seem to be acceptable ones on which to measure community compliance with regulations. On the other hand, if such measures are surrogates for the actual culprit(s), it can be argued that community compliance with regulations that are based on PM10 and PM2.5 might not guarantee that adverse health effects are adequately controlled.

VI. Summary and Conclusions

Attendees of the Second Colloquium on Particulate Air Pollution and Health offered over 160 suggestions related to needed research. These suggestions were reduced to approximately 50 focussed topics for research. Most of the projects suggested fell into three categories: "Epidemiology and Epidemiologic Methods"; "Toxicology"; and "Sampling, Analysis and Exposure Assessment". In addition, projects in areas labeled "Clinical", "Occupational", and "Dosimetry" were identified. More than half-a-dozen practical suggestions were also offered. When examined in-toto, the suggestions imply that a great deal can still be learned about linking exposure to particulate matter with human health. Some of the research is costly, perhaps impossibly so, unless new approaches, better coordination, and increased funding occur. However, the list of suggestions represent a coordinated attack on understanding the associations between particulate air pollution and human health. Also, one is struck with the practicality of the suggestions, as none appear to be unrealistic, given our current scientific expertise. The research, if substantially conducted, can be applied to providing a more healthful future for people everywhere.

VII. Reference

1. Phalen, R.F.; McClellan, R.O.: PM10 Research Needs. Inhal. Toxicol. 7(5): 773-779 (1995).

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